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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,920	09/23/2003	David W. Morris	20366-066001; PP23362.000	2631

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,920	MORRIS ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Prior to setting forth the restriction requirement, it is noted that the claims recite improper Markush Groups. M.P.E.P. 803.02 states that "Since the decisions in *in re Weber,* 580 F,2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas,* 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, *unless the subject matter in a claim lacks unity of invention* [emphasis added], *In re Harnish,* 631, F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi,* 3 USPQ 2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility." In the instant case, the methods and products rely upon polynucleotides, polynucleotides, polypeptides and antibodies which differ in both structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered to lack a substantial structural feature disclosed as being essential to the disclosed utility.

2. The claims contain a number of sequences. With the election of Groups I-XVII Applicants are required to *further elect one sequence*, SEQ ID number. Applicants are put on notice *this is not a species election.*

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 and 9-12, drawn to an isolated nucleic acid, respectively, classified in class 536, subclass 23.5.

II. Claims 8, drawn to an antisense fragment corresponding to the sequences of claim 1, respectively, classified in class 536, subclass 24.5.

III. Claims 13-15, drawn to a microarray for detecting a cancer associated (CA) nucleic acid comprising a nucleic acid sequence, respectively, classified in class 369, subclass 30.39.

IV. Claims 16-21, drawn to a polypeptide encoded by one of the polynucleotides of claim 1, respectively, classified in class 530, subclass 350.

V. Claims 22-39, drawn to an antibody that binds to a polypeptide, respectively, and the hybridoma that produces the distinct antibody and a pharmaceutical composition comprising individual antibody, respectively, classified in class 530, subclass 387.1.

VI. Claims 40 and 41, drawn to a kit for detecting cancer cells comprising an antibody, respectively, classified in class 530, subclass 388.2.

VII. Claims 42 and 56, drawn to a method for detecting cancer associated with the presence of an antibody comprising detecting the level of an antibody against an antigenic polypeptide, respectively, classified in class 436, subclass 174.

VIII. Claims 43 and 44, drawn to a method inhibiting cancer cell growth

comprising administering an antibody composition, respectively, classified in class 424, subclass 178.1.

IX. Claims 45 and 46, drawn to a kit for detecting cancer cells comprising a polynucleotide that hybridizes to a CA polynucleotide sequence, respectively, classified in class 435, subclass 6.

X. Claims 47 and 48, drawn to an electronic library comprising a polynucleotide, respectively, classified in class 700, subclass 214.

XI. Claim 49, drawn to an electronic library comprising a polypeptide, respectively, classified in class 700, subclass 214.

XII. Claims 50-53, drawn to a method for screening for anticancer activity in a potential drug comprising providing a cell that express a CA gene, respectively, classified in class 435, subclass 6.

XIII. Claim 54, drawn to a method for detecting cancer associated with expression of a polypeptide in a test sample comprising detecting a level of expression of at least one polypeptide, respectively, classified in class 436, subclass 63.

XIV. Claim 55, drawn to a method for detecting cancer associated with expression of polypeptide in a test sample comprising detecting a level of activity of at least one polypeptide, respectively, classified in class 436, subclass 86.

XV. Claims 57-60, drawn to a method of screening for a bioactive agent capable of modulating the activity of a CA protein (CAP), respectively,

classified in class 424, subclass 130.1.

XVI. Claim 61, drawn to a method for diagnosing cancer comprising determining the expression of a nucleic acid sequence, respectively, classified in class 424, subclass 9.1.

XVII. Claim 62-66, drawn to a method for treating cancers comprising administering to a patient an inhibitor of a CAP encoded by a nucleic acid sequence, respectively, classified in class 514, subclass 1.

4. The inventions are distinct, each from the other because of the following reasons:

Groups I-VI and IX-XI are structurally and functionally different products, which are made by different methods and have different uses. In the instant case, the nucleic acids of Group I is deoxyribonucleic acids (DNA), unbranched polymers composed of four subunits. Group II is drawn to an antisense fragment wherein they are a sequence of nucleotides that is a complement of the message sense. The microarray of Group III is a collection of microscopic DNA or polypeptide spots attached to a solid surface, such as glass, plastic or silicon chip forming an array. The proteins of Group IV are a linear order of amino acid residues. The antibodies of Group V are a complex of glycoproteins. And the kits of Groups VI and IX include components required for methods of detection. And the electronic library of Groups X and XI is a library in which a significant proportion of the resources are available in machine-readable format (as opposed to print or microform), accessible by means of computers. Each product is made by different methods.

The methods of Groups VII, VIII and XII-XVII differ in the method objectives, method steps and parameters and in the reagents used.

The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

Inventions VII, VIII and XII-XVII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP. 806.04, MPEP. 808.01). In the instant case the *in vitro* methods of Inventions VII and XII-XVI are distinct and independent from the *in vivo* methods of Inventions VIII and XVII and are not useable or searchable together.

Inventions X and XI are related to Groups XII-XVI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP. 806.05(h)). In the instant case the electronic library products of Group X and XI could be used in any of the methods of Groups XII-XVI.

Invention III are unrelated to Invention XIII-XV and XVII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP. 806.04, MPEP. 808.01). In the instant case the method Groups of XIII-XV and XVII cannot use

the microarray of the Group III, thus not useable nor searchable together.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
20 June 2006